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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,510	11/24/2003	Richard D. Gresham	2877	4596

7590 09/18/2007  
Kimberly V. Perry  
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EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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09/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

88

**Office Action Summary**

Application No.

10/720,510

Applicant(s)

GRESHAM ET AL.

Examiner

Michael G. Mendoza

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Response to Arguments***

1. Applicant's arguments filed 6/22/2007 have been fully considered but they are not persuasive. The applicant argues Carlson does not teach that an incision is made prior to insertion of a dilation assembly. The examiner agrees. An incision is made by 36 prior to the dilation assembly 12 being inserted. As shown in fig. 19 and 20, both a blunt introducer and expansion assembly, having a tubular member are in the lumen of the dilation assembly (combination of 92 & 94 or 82 & 84).

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-13 and 17-25 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-10, 12, 14,

Art Unit: 3734

15, 32-50 of copending Application No. 10/484749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations set forth in claims 1-11 and 17-25 of the instant application are also claimed in the patent, e.g., a radially expandable dilation assembly having a radially expandable sleeve body defining a lumen having a first cross-sectional area and a handle portion, the handle defining an aperture formed therein, an expansion assembly including an expansion member having an axial lumen with a second cross sectional area, wherein the expansion member is configured and dimensioned to be selectively receivable within the aperture formed in the handle portion; wherein the expansion member included at least one radially projection element provided on an outer surface thereof, wherein at least one radially projecting element tents the sleeve body radially outward upon insertion of the expansion member through the handle portion.

4. As to claim 12, the copending Application fails to teach wherein the distal end of the dilator is tapered. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to taper the dilator as recited in the claim because the particulars of the dilator are a mere design choice obtained through routine observation and experimentation. Furthermore, it is well known in the art of surgery to taper an end of an instrument that is being inserted into a body to provide atraumatic entry.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 3734

5. Claims 14-16 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 1-4, 6-10, 12, 14, 15, 32-50 in view of Carlson et al. 5827319.

6. The copending Application fails to specifically teach wherein the dilator has a length such that when the dilator is received within the lumen of the tubular member, the tapered distal end thereof extends beyond a distal end of the tubular member.

7. Carlson et al. teaches a device wherein the dilator has a length such that when the dilator is received within the lumen of the tubular member, the tapered distal end thereof extends beyond a distal end of the tubular member (fig. 20 & 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dilator of Carlson et al. with the tubular member of the Application to maintain an open lumen. If the dilator is did not have a length that did not extend past the tubular member the tubular member distal end would not be fully expanded. Carlson et al. teaches a converter 142.

This is a provisional obviousness-type double patenting rejection.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson et al. 5827319.

Art Unit: 3734

10. Carlson et al. teaches a method of providing access through an opening in the body of a patient, comprising: making a skin incision; inserting into the skin incision a dilation assembly, having a radially expandable sheath defining a lumen and a blunt introducer disposed in the lumen; removing the blunt introducer from the lumen; and introducing an expansion assembly, having a tubular member into the lumen of the dilation assembly to radially expand the lumen of the dilation assembly and the incision in the body of the patient; and wherein a dilator is disposed in the tubular member when the expansion assembly is introduced into the lumen of the dilation assembly (see figs. 18-21); wherein the dilation assembly further includes a handle assembly operatively coupled to a proximal end of the expandable sheath, the handle assembly defining an aperture formed therein and includes a first thread defined on the handle in the aperture thereof (inside of 50); wherein the tubular member includes an outer surface defining a second thread 48, the second thread being arranged for engaging the first thread (see fig. 3).

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



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SUPERVISORY PATENT EXAMINER